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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,158	02/05/2002	Fredene Joseph Klag	RD-27,308-6	9737

7999

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EXAMINER

FIORELLA, CHRISTOPHER A

ART UNIT

PAPER NUMBER

1731

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/068,158	Applicant(s) KLUG ET AL.
Examiner Christopher A. Fiorita	Art Unit 1731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 18-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-14 and 18-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,368,525.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ mainly in that the patent does not disclose the well known step of removing the cast material from the mold which would have been obvious to one skilled in the art at the time of the invention. Removal of the cast article from the mold would be desirable first because the article would not be useful while it is still in a mold and further, removal from the mold prior to freeze drying would expose more surface area of the molded article thus optimizing drying.

3. Applicant's arguments filed 11/10/03 have been fully considered but they are not persuasive.

With respect to the double patenting rejection applicant argues:

Claims 1-14 and 18-29 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,368,525 (hereinafter referred to as "525 patent"). The Examiner states

that the conflicting claims are not patentably distinct from each other "because the claims differ mainly in the obvious step of removing the cast material from the mold." Applicants submit that, in order to establish a *prima facie* case of obviousness: there must be some suggestion or motivation to modify the reference. The requisite suggestion or motivation must come from the references themselves rather than from the Applicants' specification. Evidence of obviousness must show a specific teaching, motivation, or suggestion in the prior art to make the specific combination that was made by the Applicants. See In re Sang Su Lee, 61 U.S.P.Q.2d 1430 (.Fed. Cir. 2002). Accordingly, Applicants submit that such suggestion or motivation to modify the reference be cited by the Examiner.

Applicants submit that the reference cited by the Examiner neither teaches nor suggests removal of the gel-cast ceramic article from the mold prior to freezing, but instead is silent with respect to removal of the cast material. Applicants therefore submit that the '525 patent fails to provide the requisite specific teaching, motivation, or suggestion, and that the provisional rejection of Claims 1-14 and 18-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the reference is successfully overcome.

This argument is not persuasive. It is recognized that the '525 patent does not teach the step of removing the molded body from the mold. MPEP allows for making a statutory double patenting rejection without citing an additional reference. See MPEP 804. It is maintained that the well known step of removing the cast material from the mold which would have been obvious to one skilled in the art at the time of the invention. Removal of the cast article from the mold would be desirable first because the article would not be useful while it is still in a mold and further, removal from the mold prior to freeze drying would expose more surface area of the molded article thus optimizing drying.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents establish that it is notoriously well known in the art to remove a molded article from a mold prior to freeze drying.

Neri et al. (4,992,220) teaches removing a gelled mixture from a mold after which it is freeze dried (see abstract).

Pathak (2003/0077272) teaches removing a polymerized article from a mold and then freeze drying. See paragraph [0087].

Watt (2002/0010482) teaches removing a molded body from a mold and then freeze drying. See paragraph [0037].

Larsson (5,989,492) teaches releasing a molded body from a mold and then freeze drying the body. See col. 1, lines 45-50.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Fiorilla whose telephone number is (571) 272-1187. The examiner can normally be reached on M-F, 6:30am-3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin can be reached on (571) 272-1189. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Christopher A. Fiorilla
Primary Examiner
Art Unit 1731

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